

#### FORM 6-K

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Report of Foreign Private Issuer

Pursuant to Rule 13a - 16 or 15d - 16 of the Securities Exchange Act of 1934

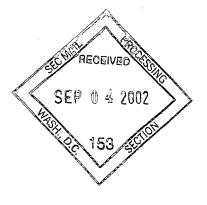
For the month of September 2002



(Translation of registrant's name into English)

Oakdene Court
613 Reading Road
Winnersh
Wokingham, Berkshire RG41 5UA
United Kingdom

(Address of principal executive offices)



PROCESSED

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THOMSON FINANCIAL

(Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F).

Form 20-F X Form 40-F

(Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934).

Yes \_ No X

(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_).

Enclosure: Press release dated September 3, 2002 announcing the successful outcome of the

Company's clinical trial of frovatriptan for use in preventing menstrual migraines.

## **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant, Vernalis Group plc, has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 3rd, 2002

**VERNALIS GROUP PLC** 

Richard J. Robinski Company Secretary



# Press Release

3 September 2002

# Frovatriptan highly effective in preventing menstrual migraine Positive results from US Phase IV trial

Vemalis Group plc ("Vernalis" LSE: VER) today announced the successful outcome of a large multi-centre study that demonstrated the significant benefits of using frovatriptan, its newly marketed anti-migraine treatment, in the prophylaxis (prevention) of menstrually-associated migraine headaches.

The double-blind, placebo-controlled crossover trial was conducted at 36 clinics in the United States and involved over 500 menstrual migraine sufferers. On average, women in the trial had suffered between 11 and 12 menstrual migraine attacks over the previous 12 months and had a 12-year history of menstrually-associated migraine.

Patients were evaluated over three menstrual cycles over the course of which each patient received all three dose regimens, placebo, 2.5mg frovatriptan and 5mg frovatriptan, in randomised order. During each cycle they took the treatment for a total of six days commencing before the predicted onset of their headache.

The headline results showed that both dose levels of frovatriptan were highly effective in reducing the incidence, severity, and duration of menstrually-associated migraines compared to placebo.

52% of patients were completely headache-free during the six-day period when they took 5mg frovatriptan daily, and 41% were headache-free at a daily dose of 2.5mg, compared to only 26% when they took placebo. These differences were highly statistically significant (p<0.0001). In addition, there were statistically significant reductions in the severity of the attacks and in the duration of headaches, and a concomitant decrease in patients' functional impairment. Frovatriptan was well tolerated during the trial and the adverse event profile was similar to that previously seen with single doses of frovatriptan.

Around 16% of women suffer from migraines and recent studies suggest that as many as 50% of female migraineurs report that menstruation is a trigger for their migraine attacks (MacGregor et al.). One possible explanation is that the hormonal changes which are believed to be the trigger for menstrually-associated migraine continue over a number of days.

Commenting on the results, Dr John Hutchlson, Vernalis's Chief Medical Officer said "We already know that frovatriptan is effective as an acute treatment for migraine, and the results of this study confirm our belief that, with its 26-hour half-life in blood, it could also be ideally suited for use as a prophylactic treatment for menstrual migraine. We will be conducting further clinical studies to develop this new indication and to realise the enormous potential benefits of this breakthrough for menstrual migraine sufferers."

Robert Mansfield, Chief Executive of Vernalis, said "These exciting data on menstrual migraine add an entirely new dimension for trovatriptan. The fact that frovatriptan has the longest half-life clearly differentiates it in the class of triptan drugs. We are very pleased with the progress and the feedback from the frovatriptan launch in the US."

Dr Anne MacGregor, Director of the City of London Migraine Clinic, commented "This is a very positive set of results in this population with menstrually-associated migraine. Existing treatments do not work as well in menstrual migraine attacks, and there is a real need for effective and specific prophylactic treatments."

Dr Arthur Elkind, Director of the Elkind Headache Center in New York, said "The data from this trial look most impressive and we can look forward to confirmation of the results in future studies. A number of my patients were eager to continue with frovatriptan as a preventative treatment once they had completed the trial."

Frovatriptan, a 5-HT<sub>1BO</sub> agonist, was developed by Vernalis and is already approved in the US and the European Union for the acute treatment of migraine.

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This press release contains forward-looking statements, including statements regarding Vernalis' strategy and prospects. Statements that are not historical facts are based on Vernalis' current expectations, beliefs, estimates and assumptions. Such statements are not guarantees of future performance and involve risks, uncertainties and other important factors that may cause Vernalis' actual results, performance or achievements to be materially different from those anticipated by such forward-looking statements. Important factors which may affect Vernalis' future operating results include the following: Vernalis may not receive royalty revenues, milestone payments or other revenues when expected or at all, Vernalis' product candidates may not receive regulatory or marketing approval or gain market acceptance in key markets when anticipated or at all, Vernalis may be unable to conduct its clinical trials as quickly as it has predicted, Vernalis' product candidates may not demonstrate therapeutic efficacy, Vernalis may be unable to obtain sufficient capital when needed to develop its product candidates, and other important factors described in the section entitled "Flisk Factors" in Vernalis' Registration Statement on Form 20-F filed with the US Securities and Exchange Commission.

#### Enquiries:

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For previous press releases please see the Vernalis website: www.vernalis.com

#### **Notes to Editors**

### Menstrual Migraine

Migraine is a common neurological disorder affecting more women (13-18%) than men (3-6%) are affected and the prevalence increases up to the age of 40, declining thereafter. Menstrually-associated migraine is that which occurs at or around the time of menstruation. It is well recognized that the character of menstrually-associated migraine tends to differ from other migraines in that it lasts longer and is generally more resistant to treatment and more likely to reoccur.

According to the National Headache Foundation, migraine is such a pervasive problem that 157 million workdays are lost each year in the US. The per-patient annual costs associated with migraine have been estimated at \$6,684 for male and \$3,600 for female migraine sufferers. American industry loses an estimated \$50 billion annually due to absenteeism and medical costs from headaches, which include migraine.

#### Vernalis

Vernalis is an integrated biopharmaceutical company that discovers, develops and commercialises drugs to treat central nervous system diseases, obesity and related disorders. The Company is internationally recognised for its expertise in the field of serotonin, a key neurotransmitter involved in neurological, psychiatric and eating disorders.

The Vernalis portfolio includes programmes targeting sexual dysfunction, obesity, diabetes, Parkinson's disease, depression and anxiety. Vernalis shares trade on the London Stock Exchange (VER) and the website is located at www.vernalis.com.

#### References:

MacGregor EA, Chia H, Vohrah RC and Wilkinson M. (1990) Migraine and menstruation: a pilot study. *Cephalalgia* 10, 305-310.